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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

VRETTAKOS, PETER J

ART UNIT PAPER NUMBER

3739

DATE MAILED: 02/11/2004

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/917,811

Applicant(s)

ZVULONI ET AL.

Examiner

Peter J Vrettakos

Art Unit

3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 January 2004.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-154 is/are pending in the application.
4a) Of the above claim(s) 34-148 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-33, 149, 150 and 152-154 is/are rejected.
7) ☒ Claim(s) 151 is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

An RCE has been filed 1-20-04. The following action is non-final.

The Applicant has made minor amendments to the claims in Amendment B dated 12-31-03, and the Examiner has pointed out, *infra*, excerpts in the prior art (Holupka et al.) that anticipates or makes obvious the claims in their amended configuration. The Response to Arguments section below carefully elaborates the Examiner's positions.

Claims 34-39 are newly introduced in Amendment B. **This is in error.** The claims should be instead 149-154. **Claims 34-148 are still pending (withdrawn).**

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 1-23, 27, 28, 33, 149-150, and 152-154 are rejected under 35 U.S.C. 102(e) as being anticipated by Holupka et al. ('529).

Independent claim 1

Holupka discloses a planning system for planning a cryosurgical ablation procedure (col. 10:28-33), comprising: a first imaging modality (col. 4: 24-26 and col. 4:

44-47) for creating digitized preparatory images of an intervention site; a three dimensional modeler (14, col. 4:34-40) for creating a three dimensional model of the intervention site based on the digitized preparatory images; and a simulator (13,col. 4:35-40) for simulating a cryosurgical intervention, which comprises an interface useable by an operator for specifying loci for insertion of cryoprobes (19, patented claim 4) and operational parameters (col. 7:56-63) for operation of cryoprobes for cryoablating tissues; and a displayer for displaying in a common virtual space an integrated image comprising a display of the three dimensional model of the intervention site and a virtual display of cryoprobes inserted at the loci (col. 8:7-9). SEE PATENTED CLAIMS.

Dependent Claims

Re: claim 2, Holupka discloses a memory for storing loci for insertion and operational parameters (col. 6:8-10).

Re: claim 3, Holupka discloses a method of computerized tomography, MRI and ultrasound imaging (col. 4: 23-26).

Re: claim 4: the use of a Cartesian coordinate system to express a 3-D model is a ubiquitous act throughout the scientific modeling community in the majority of fields, including medicine.

Re: claims 5-10, Holupka discloses the ability to highlight selected regions within the 3-D model. Holupka also discloses markers (18, col. 7: 25-33) for the images generated by the MRI or ultrasound devices allowing the modeler to subsequently

generate images of the tissue to be cryoablated, as well as the tissue (ex. rectum, bladder) to be protected.

Re: claims 11-15, 149-150, and 152, Holupka implicitly discloses different zones (targeted vs. non-targeted) of relevance to the operation. The demarcation of zones by Holupka is equivalent to disclosing a predictor for predicting probe effects on tissue. Holupka is able to define the specific dimensions of the disclosed zones for each surgery, thereby allowing the operator to better control the destruction of targeted tissue while preserving non-targeted tissue.

Re: claims 4, 16-22, and 153-154, Holupka discloses an apparatus capable of 3-D modeling used to control the placement and operation of the cryoprobe, thereby indicating that the images (**which can be manipulated by the operator**; col. 6:47-63) provide a *recommended* course of action for the impending surgery. The recommended course of action would inherently (because the following parameters are extant in all cryosurgical procedures) include parameters such as the optimal number of cryoprobes, temperature, duration of cooling, specific locations for insertion, etc.

Re: claims 23, 27, 28, and 33, Holupka discloses cryosurgical (patented claim 23) prostate (see figure 1a) ablation.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to

a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 24,25, and 29-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holupka in view of Mikus et al. ('690).

Holupka neglects to disclose cryosurgical prostate treatment toward BPH.

Mikus et al. discloses, *inter alia*, a cryosurgical prostate treatment toward BPH (col. 1:15-18; col. 2:57). Also disclosed is *percutaneous* prostate cryoablation (col. 3:56).

Therefore, at the time of the invention it would have been obvious to modify Holupka in view of Mikus et al. by including as protocol treatment for the prostate. The motivation would be to provide an additional application for the Holupka ablation system.

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Holupka in view of Mikus et al. ('690) and further in view of Crockett ('488).

Holupka and Mikus neglect to explicitly disclose *transperineal* cryosurgical prostate treatment (col. 3: 65-67).

Crockett discloses *transperineal* cryosurgical prostate treatment.

Therefore, at the time of the invention it would have been obvious to modify Holupka in view of Mikus et al. and further in view of Crockett by including as protocol *transperineal* treatment for the prostate. The motivation would be to provide an additional application for the Holupka ablation system.

Claims 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holupka in view of Mikus et al. ('690) and further in view of Fenn et al. ('426).

Holupka and Mikus neglect to explicitly disclose the use of AUA scores in conjunction with prostate cryoablation.

Fenn et al. discloses the use of AUA scores in conjunction with prostate cryoablation.

Therefore, at the time of the invention it would have been obvious to modify Holupka in view of Mikus et al. and further in view of Fenn et al. by including AUA scores in the protocol. The motivation would be to provide better treatment by using a commonly used indicator of prostate tissue health.

Response to Arguments

Applicant's arguments filed 1-20-04 have been fully considered but they are not persuasive.

The Applicant has inserted into independent claim 1 language that the loci for insertion of the cryoprobes are operator-specified. The Examiner respectfully disagrees. Holupka discloses operator manipulation of images in col. 6:47-63. By editing the image acquired, the operator ultimately affects the pre-determined "optimal" placement of probes. For example, deleting a contour from an image will inherently change the pre-determined optimal placement of probes and dosage (parameter for operation of probes that can be changed/ "supplied" by the operator through image manipulation)

characterized by the Holupka planning system. Therefore, the loci for insertion of the cryoprobes is operator-specified through image manipulation.

The direct correlation between the data that is used to generate an image and the determined optimal positions of the seeds/probes is found in col. 2:36-38. The excerpt indicates that the image at least partially impacts the system-determined optimal positions of probes. Therefore, anything that changes the image theoretically changes the pre-determined optimal positions and dosage.

Further, by editing images the operator is "recommending" and "predicting" cryoablation procedures because the optimal placement of probes and dosage determined is resultantly changed.

The Applicant has obviated through Amendment B the prior **35 USC § 112** rejections.

Allowable Subject Matter


Claim 151 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art neglects to disclose a cryosurgical planning system capable of predicting the size and shape of the prostate two or more weeks after operation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J Vrettakos whose telephone number is 703 605 0215. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C Dvorak can be reached on 703 308 0994. The fax phone numbers for the organization where this application or proceeding is assigned are 703 746 7013 for regular communications and 703 746 7013 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308 0858.

Pete Vrettakos
February 9, 2004



ROY D. GIBSON
PRIMARY EXAMINER